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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,811	11/25/2003	Charles Hensley	33205.0217	8179

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,811	HENSLEY ET AL.	
	Examiner	Art Unit	
	John Pak	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14,16-19,22,41 and 43-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14,16-19,22,41 and 43-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/29/2008 has been entered.

Applicant's terminal disclaimer, filed on 7/30/2008, has been reviewed. The terminal disclaimer is improper for the reasons stated below. A paragraph from the terminal disclaimer is reproduced below with markings to explain the problem.

> Zicam, LLC, is the sole owner of the instant application, the same as the owner of United States Patent No. 6,673,835, and copending Application Nos. 11/781,396; 11/748,668; 11/748,653; and 11/749,111. Zicam, LLC, hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend it beyond the expiration date of the full statutory term defined in 35 U.S.C. §§ 154-156 and 173, as presently shortened by any terminal disclaimer, of prior U.S. Patent No. 6,673,835 and patents that issue on Application Nos. 11/781,396; 11/748,668; 11/748,653; and 11/749,111. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent(s) are commonly owned.

The disclaimer agrees that any patent granted on the instant application shall be enforceable only for and during the period that it and the prior patent(s) are commonly owned. This is the problem. A proper disclaimer must agree that any patent granted on the instant application shall be enforceable only for and during the period that all

patent(s), i.e. not just the prior patent(s), that have issued and may issue in the future from all the listed applications are commonly owned.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 14, 16-19, 22, 41, 43-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been reviewed again, and upon reconsideration, certain indefiniteness issues have been noted.

(1) The full metes and bounds of "agent to increase diffusion of the active substance through mucous in the nasal passage" (emphases added) and "permeation enhancer" are unclear. Both ingredients, i.e. said agent to increase diffusion and said permeation enhancer, seem to be similar such that it would be unclear to the skilled artisan in this field which ingredient is covered by which claimed feature and where the metes and bounds of such ingredients are.

It is duly noted that the specification describes liposomes, chitosan, cyclodextrin, protease inhibitors, ascorbic acid in water, glycerol in water as permeation enhancers (page 13, lines 9-10; page 15, lines 22-23; paragraph bridging pages 15-16) and glycerin as an agent to “permit zinc ions to readily diffuse therethrough” (emphasis added) and permeate mucous (page 9, lines 10-13). NaCl is disclosed to "facilitate the

diffusion of zinc through the layer of mucous" (page 21, lines 22-27) (emphasis added). However, such examples do little to inform the skilled artisan in this field which other ingredients could be considered to be within the ambit of said agent to increase diffusion or said permeation enhancer.

(2) Applicant has argued in the remarks accompanying the RCE (7/30/2008) that it is the carrier, not the composition, that comprises about 75-99 wt% water and about 0.000001-5 wt% thickening agent. However, this appears to be in error.

First, the language of dependent claim 44 contradicts applicant's argument. Claim 44 recites a gel composition that contains 0.000001-5 wt% thickening agent – i.e. the percentage is based on the composition per se and is not based on the carrier component of the composition.

Second, the specification seems to disclose the convey the thickener concentration on a composition basis. See for example page 15, lines 24-27:

> Hydroxycellulose or other thickeners or components can, if desired, be utilized to form colloidal solutions (i.e., suspensions) in order to increase the viscosity of the carrier in the nasal gel composition. The presently preferred concentration for thickeners is 0.000001% to 5.0% by weight.

Absence of carrier mention here (i.e. absence of the mention that the above percentage range is based on the 75-99.8% of the carrier, not of the entire composition) conveys that the percentage is for the composition per se.

Consequently, the claims are still confusing, especially in light of applicant's contradictory arguments and contradictory dependent claim. See the full reasons stated

in the previous Office action of 4/1/2008, page 2. Precise interpretation of the claimed percentage ranges is required but applicant's imprecise language and incorrect arguments have compounded the indefiniteness of the instant claims.

(* Applicant should note that claim 44 could be a duplicate claim or an improperly dependent claim depending on how independent claim 11 is interpreted. Appropriate correction should be made).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 16-19, 22, 41, 43-45, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eby, III (Re. 33,465, hereinafter referred to as “Eby”) in view of ES 2095183, HCAPLUS abstract 1994:638216, further in view of DE 3431727 (full English translation already of record).

Eby teaches reduction in the duration of common cold symptoms such as nasal drainage, nasal obstruction, sore throat, fever, cough, which are the result of upper respiratory infection (column 2, lines 57-64) by applying to the nasal mucosal membrane a zinc compound (column 2, lines 64-68). Nasal sprays, nasal drops, nasal ointments, nasal washes and nasal injections are taught (column 3, lines 3-7). Zinc gluconate is taught (column 3, line 24).

ES 2095183 discloses a drug delivery system composed of aqueous preparations that have a liquid form at room temperature but become gels at body temperature and adhere to the nasal mucosa (see the English abstract, HCAPLUS abstract 1997:283905). Less than 1% bioadhesive polymer such as hydroxypropyl cellulose and sodium chloride for isotonicity is disclosed (id.). Advantage of the gel intranasal delivery is controlled delivery (id.).

HCAPLUS abstract 1994:638216 discloses that bioavailability of nasally applied drugs is reduced by nasal mucociliary clearance, so nasal solutions contain polymers as thickeners to prolong the time between drug and the mucosa. Methyl hydroxypropyl cellulose and gellan gum (polysaccharide, i.e. a carbohydrate) are known thickeners in solutions of drugs that are applied nasally. The gellan gum is advantageous in that its viscosity increases when physiological level of cations are present.

DE 3431727 discloses that nasally applied zinc gluconate for treating viral ailments such as the common cold is at a concentration of 0.1 to preferably 2% (page 3 of translation, claims 1-2; page 6 of translation, last paragraph).

Eby does not expressly disclose every claim limitation or feature recited in the instant claims. Discussion of each feature and suggestion from the cited prior art is set forth below.

"A composition for delivering an active substance to a nasal membrane":

Eby provides the motivation to deliver Zn gluconate nasally. Nasal sprays, nasal drops, nasal ointments, nasal washes and nasal injections are taught (column 3, lines 3-7).

"about" 0.185 to 2.8 wt% zinc gluconate, "about" 0.9 to 2 wt% ionizable zinc salt, "about" 4 to 60 mM zinc ion, "about" 20-44 mM zinc ion:

Although Eby does not expressly disclose these concentrations, Eby teaches the nasal administration of zinc to treat the symptoms of the common cold. DE 3431727 provides the motivation to nasally administer zinc gluconate for treating viral ailments such as the common cold at a concentration of 0.1 to 2% (page 3, claims 1-2; page 6, last paragraph). 0.1% zinc gluconate calculates to about 2.2 mM and 2% zinc gluconate calculates to about 44 mM.

Motivation to select the drug delivery system of ES 2095183:

Eby discloses nasal sprays, drops, nasal ointments, but Eby does not provide a specific formulation disclosure for nasal administration. Hence, the ordinary skilled artisan would have looked to nasal delivery technology that was available before applicant's effective filing date. ES 2095183 teaches that its aqueous drug delivery preparation is a liquid at room temperature but gels at body temperature and adheres to the nasal mucosa, thereby providing controlled delivery of active drugs. The ordinary skilled artisan would have been motivated to formulate zinc gluconate as taught by ES 2095183 with the expectation that zinc gluconate would be conveniently administered as a liquid that gels in the nasal mucosa to provide controlled delivery of the zinc to treat

the common cold. The ordinary skilled artisan would have been further motivated from HCAPLUS abstract 1994:638216 that bioadhesives such as those utilized in ES 2095183 advantageously prolong the contact time between the mucosa and the delivered drug.

Agent to increase diffusion of the active substance through mucous in the nasal passage:

The drug delivery formulation of ES 2095813 contains sodium chloride to provide isotonicity.

Thickening agent, 0.000001 to 5 wt%: The drug delivery formulation of ES 2095813 contains bioadhesive polymers such as cellulose derivatives at an amount that is less than 1%. The example on page 3, column 4, lines 35-49 of ES 2095183 discloses 0.2 g of hydroxypropylmethylcellulose in 100 ml of water, i.e. 0.2 wt%.

Hydroxyethylcellulose as the thickening agent: From the general bioadhesive teaching to the specific hydroxypropylcellulose exemplified by ES 2095813, hydroxyethylcellulose would have been an obvious modification since both cellulose derivatives are structurally similar cellulose ethers. Motivation to make the modification arises from the advantages of utilizing similar bioadhesive polymers to provide controlled delivery of the active substance.

75-99.8 wt% carrier, water being present at 75-99 wt%: Different interpretations of this feature have already been set forth. The example on page 3, column 4, lines 35-49 of ES 2095183 discloses 12.15 g of ingredients in water to make up 100 ml. Even the English abstract of ES 2095183 shows weight amounts of other ingredients that

would calculate to a water amount that is within applicant's claimed amount range. Therefore, such amount of water falls within applicant's water amount.

Permeation enhancer: The drug delivery formulation of ES 2095813 contains benzyl alcohol. An alcohol would provide solvent properties and would thus provide permeation enhancement.

A system for applying the composition to a nasal membrane:

Nothing more than an applicator and the composition is required in applicant's system, so a mere container and a means for applying Hersh's gel would meet this claim feature. One having ordinary skill in the art would have been motivated to provide the gel in a container and then use some means to apply the gel to the route of administration. The "system" is thereby fairly suggested.

Viscosity of the composition is between 2,500 and 40,000 cp or 5,000 and 20,000 cp

First, it must be noted that a viscosity feature without specificity as to temperature is substantially meaningless. For example, a difference of mere 20°C can result in viscosity difference of more than five thousand fold[1]. Hence, the composition suggested by the prior art could and would have the claimed viscosity at some temperature, since viscosity varies with temperature.

Second, *and in the alternative*, it would have been recognized by the ordinary skilled artisan that the claimed viscosity, at room temperature, would have had the

[1] Macmillan Encyclopedia of Physics. See glycerin at 20°C and 40°C.

consistency and viscosity of common substances such as honey or mayonnaise[2]. Since Eby has taught that "method of application that does not maintain a sufficiently high level of zinc ions in the locus of treatment would not prevent continued viral replications" (column 2, lines 30-33), and the secondary references teach the advantage of polymers and thickeners such as those used by applicant to prolong the time an active agent remains in the intranasal locus, a level of viscosity such as the range now claimed in claims 49-50 would have been obvious because such viscosity range would have been expected to be beneficial in maintaining the zinc ion in the locus without substantially adverse runoff.

In sum, the ordinary skilled artisan would have been motivated to select the nasal delivery formulation of ES 2095183 to nasally deliver Eby's zinc gluconate to treat symptoms of the common cold because said nasal delivery formulation would have been expected to provide the advantages of controlled delivery and prolonged contact time in the mucosa. Inclusion and utilization of all other ingredients and features are fairly suggested as discussed above. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

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[2] www.popemixers.com/downloads/General_ViscosityTable.pdf. Retrieved from the Internet on 11/8/2006.

Applicant's arguments relative hereto have been given due consideration, but they were deemed unpersuasive.

Applicant argues again that there is no suggestion to combine the references to form the claimed invention. Applicant argues that Eby does not suggest looking at other nasal application technologies, and even if that were not the case, combination with ES 2095185 would still not have been suggested because Eby disclosed other technologies, which were stated as being ineffective.

The Examiner must disagree. Eby discloses that prior art formulations are ineffective because "natural circulation removes zinc ions from the locus of the treatment more rapidly than the low application rate of zinc ions by the dosage replaces them" (column 2, lines 20-26). Eby further discloses, "method of application that does not maintain a sufficiently high level of zinc ions in the locus of treatment would not prevent continued viral replications (column 2, lines 30-33). Clearly, Eby suggests utilizing a nasal application technology that maintains the delivery of zinc ions at a high enough level to have an effect, which level is not removed in excess by the natural process. Considering that nasal application is inherently susceptible to runoff problems, Eby's teachings directly points to use of nasal application technology like the one taught by ES 2095183, which would adhere to the nasal mucosa and provide controlled delivery of an active ingredient. One having ordinary skill in the art, at a time prior to applicant's effective filing date, would have recognized the advantage that such nasal

application technology provides and would thus have found it obvious to use the same to deliver Eby's nasal active ingredient.

For these reasons, this ground of rejection must be maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 17-19, 22, 41 and 44-45 are again rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,673,835 in view of ES 2095183 and DE 3431727 for the reasons of record. As noted earlier in this Office action, applicant's terminal disclaimer is insufficient. Hence, this ground of rejection must be maintained.

New claims 49-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

(1) claims 1-15 of copending Application No. 11/781,396;

(2) claims 1-20 of copending Application No. 11/748,668;

(3) claims 1-18 of copending Application No. 11/748,653; and

(4) claims 1-20 of copending Application No. 11/749,111.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the same ingredients with substantially the same or similar viscosity feature are disclosed in the copending application claims. Water would have been obvious carrier/diluent in the invention of the copending application claims. Note, "about" in both the instant claims and the copending claims, which render obvious the specific viscosity ranges claimed in this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. As noted earlier in this Office action, applicant's terminal disclaimer is insufficient. Hence, these grounds of rejection must be maintained.

All grounds of rejection which have not been maintained herein from the previous Office action are withdrawn upon reconsideration and in view of applicant's amendments and remarks.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to John Pak whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616